

CLAIMS

1. A soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof characterised in that the capsule comprises gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source.
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2. A soft gelatin capsule as claimed in Claim 1 wherein formulation comprises 5, 8, 11, 14, 17-eicosapentaenoic acid (or "EPA").
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3. A soft gelatin capsule as claimed in Claim 2 wherein EPA is present in an amount of at least about 50 wt % of the formulation.
4. A soft gelatin capsule as claimed in Claim 2 or Claim 3 wherein EPA is present in an amount of between from about 50 wt % to about 60 wt % of the formulation.
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5. A soft gelatin capsule as claimed in Claim 2 or Claim 3 wherein EPA is present in an amount of at least about 90 wt % of the formulation.
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6. A soft gelatin capsule as claimed in any of the preceding claims wherein the formulation comprises 4, 7, 10, 13, 16, 19-docosahexaenoic acid (or "DHA").
7. A soft gelatin capsule as claimed in Claim 6 insofar as dependent from any of Claims 1 to 4 wherein DHA is present in an amount of between from about 20 wt % to about 30 wt % of the formulation.
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8. A soft gelatin capsule as claimed in any of the preceding claims comprising between from about 100mg to about 2000mg of said formulation.
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9. A soft gelatin capsule as claimed in any of the preceding claims comprising about 500mg of said formulation.

10. A soft gelatin capsule as claimed in any of Claims 1 to 8 comprising about 1000mg of said formulation.

11. A soft gelatin capsule as claimed in any of the preceding claims wherein the or 5 at least one omega-3 polyunsaturated fatty acid is in free acid form or in the form of a pharmacologically acceptable salt thereof.

12. A soft gelatin capsule as claimed in any of the preceding claims wherein the omega-3 polyunsaturated fatty acid is in free acid form.

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13. A soft gelatin capsule as claimed in any of the preceding claims wherein the gelatin comprises porcine gelatin.

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14. A soft gelatin capsule as claimed in any of Claims 1 to 12 wherein the gelatin comprises bovine gelatin.

15. A soft gelatin capsule as claimed in any of Claims 1 to 12 wherein the gelatin comprises fish gelatin.

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16. A soft gelatin capsule as claimed in any of the preceding claims wherein the wall of the capsule consists of a single layer.

17. A soft gelatin capsule as claimed in any of the preceding claims wherein the capsule delays release of the formulation until after passage through the stomach.

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18. A soft gelatin capsule as claimed in any of the preceding claims wherein the capsule delays release of the formulation until after passage beyond the pancreatic duct in the duodenum.

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19. A soft gelatin capsule as claimed in Claim 17 or Claim 18 wherein the capsule is coated with at least one enteric material.

20. A soft gelatin capsule as claimed in any of Claims 17 to 19 wherein at least one enteric material is integrated within the gelatin of the capsule.

21. A soft gelatin capsule as claimed in Claim 19 or Claim 20 wherein the or at least one enteric material is a neutral polyacrylate polymer.
- 5 22. A soft gelatin capsule as claimed in any of Claims 19 to 21 wherein the or at least one enteric material is poly(ethylacrylate-methylmethacrylate).
- 10 23. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in the manufacture of a medicament comprising at least one soft gelatin capsule as defined in Claim 1 for the oral treatment or prophylaxis of a condition selected from chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, bipolar disorder and neoplastic disease.
- 15 24. Use as claimed in Claim 23 wherein the medicament comprises at least one soft gelatin capsule as defined in any of Claims 2 to 22.
- 20 25. A process for the manufacture of a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof, said process comprising encapsulating said pharmaceutical formulation in gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source.
- 25 26. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof to improve resistance of the soft gelatin capsule to chemical interaction with the formulation.
- 30 27. Use as claimed in Claim 26 wherein said resistance is greater than that of a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof in which the gelatin consists essentially of gelatin extracted by an extraction process comprising alkali pre-treatment of a collagen source.

28. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof to improve shelf life of the soft gelatin capsule.
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29. Use as claimed in Claim 28 wherein said shelf life is greater than that for a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof in which the gelatin consists essentially of gelatin extracted by an extraction process comprising alkali pre-treatment of a collagen source.
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- 15 30. A method of treatment or prophylaxis of a condition selected from chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, bipolar disorder and neoplastic disease comprising administering a therapeutically effective amount of a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable salt thereof per day in the form of a plurality of soft gelatin capsules as defined in Claim 1.
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- 25 31. A method as claimed in Claim 30 wherein the soft gelatin capsules are as defined in any of Claims 2 to 22.
32. A soft gelatin capsule substantially as hereinbefore described with reference to the accompanying examples.
33. A process substantially as hereinbefore described with reference to the accompanying examples.
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34. A use substantially as hereinbefore described with reference to the accompanying examples.
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